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EXAMINER	
TANNER, JOCELIN C	

ART UNIT	PAPER NUMBER
3731	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,483	LEE ET AL.	
	Examiner	Art Unit	
	JOCELIN C. TANNER	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Amendment filed 25 November 2009. Claims 1-16 are currently pending. The Examiner acknowledges the amendments to claims 1, 4, and 13 and new claims 15 and 16.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chin (US Patent No. 5,391,182) in view of Young (US Patent No. 4,906,231).

3. Regarding claim **1**, Chin discloses a loop suture (316) that is threaded between two pieces of tissue surrounding a wound, a tightening member (310) that is capable of gathering both ends of the threaded loop suture and of exerting a pressure of wound tightening force, a pulling member (346) that is capable of pulling the loop suture, and a housing member (334) that houses the pulling member and is capable of tightening the loop suture (column 6, lines 8-19, Figs. 5F-5H). However, Chin fails to disclose a locking member.

Young teaches a device having a telescoping plunger or "pulling member" (20) within a barrel or "housing" (12) wherein a plunger guide or "locking member" (30) having guide slots (32, 33) and detents (34) that engage the ribs (22) of the pulling member, thus preventing reverse movement of the pulling member (column 2, lines 56-67, Fig. 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of Chin with a locking member, as taught by Young, to restrict movement of a device to ensure safety.

4. Regarding claim **4**, Young discloses a pulling member (20) having a first saw tooth outside surface (22, 23) and a locking member having a second saw tooth (34) on an inside surface of the locking member (30) in reverse form of the first saw tooth on the pulling member to check the movement of the pulling member to prevent slippage in an opposite direction after pulling and engaging the saw teeth of the pulling member and locking member (column 2, lines 55-67, Fig. 2).

5. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chin (US Patent No. 5,391,182) in view of Young (US Patent No. 4,906,231), as applied to claim 1 above, and further in view of Yoon (US Patent No. 5,478,353).

6. Regarding claim **2**, the combination of Chin and Young discloses all of the limitations previously discussed except for an elastic housing member.

Yoon teaches a device having a pulling member (17) telescopically disposed within a housing (19) wherein the pulling member and housing are both disposed within tubular housing (11) and are formed of elastic material (column 6, lines 9-13, Fig. 5).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the housing member of the device of the combination of Chin and Young of an elastic material, as taught by Yoon, for the predictable result of preventing trauma during treatment.

7. Regarding claim **3**, Yoon teaches a housing member (19) having a scale to allow the user to control the tension of the suture (column 9, line 34, Fig. 5).

8. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chin (US Patent No. 5,391,182) in view of Young (US Patent No. 4,906,231), as applied to claim 1 above, and further in view of Akerfeldt et al. (US Patent No. 6,860,895).

9. Regarding claims **5 and 6**, the combination of Chin and Young discloses all of the limitations previously discussed except for a strain gauging means.

Akerfeldt et al. teaches a device including a spring (166) that is connected to suture (6) via block (164) wherein the suture is released when the pulling force applied to the suture exceeds the force of the wire spring (166) (column 9, lines 63-67, column 10, lines 1-5, Fig. 12).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of the combination of Chin and Young with strain gauging means, as taught by Akerfeldt et al., to ensure safe closure of a wound and avoid the risk of rupturing a vessel.

10. Claims 7, 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chin (US Patent No. 5,391,182) in view of Young (US Patent No. 4,906,231), as applied to claim 1 above, and further in view of Murray et al. (US Patent No. 5,190,526).

11. Regarding claims **7, 8 and 10**, the combination of Chin and Young discloses all of the limitations previously discussed except for a buffering means formed of an elastic member and inserted into a predetermined position of the pulling member.

Murray et al. teaches a device including pulling member (2a) disposed within a housing member (1a) wherein a spring (3c) connects two ends of the pulling member (Figs. 8-12).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of the combination of Chin and Young with buffering means, as taught by Murray et al., to control the retraction of the pulling member.

12. **Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chin (US Patent No. 5,391,182) in view of Young (US Patent No. 4,906,231) and in view of Murray et al. (US Patent No. 5,190,526), as applied to claim 7 above, and further in view Yoon (US Patent No. 5,478,353).**

13. Regarding claim **9**, the combination of Chin, Young and Murray et al. discloses all of the limitations previously discussed except for a buffering means formed of an elastic member and inserted into a predetermined position of the housing member.

Yoon teaches a device having a pulling member (17) telescopically disposed within a housing (19) wherein a spring (69) is compressed within the housing between the end cap (65) and the pulling member (column 6, lines 1-2, Fig. 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the housing member of the device of the

combination of Chin, Young and Murray et al. with buffering means, as taught by Yoon, to inhibit unintentional proximal movement.

14. Claims 11, 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chin (US Patent No. 5,391,182) in view of Young (US Patent No. 4,906,231), as applied to claim 1 above, and further in view of Goodin et al. (US Patent No. 4,723,938).

15. Regarding claims **11 and 12**, the combination of Chin and Young discloses all of the limitations previously discussed except for a loosening means including a female nut and a bolt.

Goodin et al. teaches device including a pulling member (36) having internal threads or a "bolt" (42) that is disposed within a housing (12) having corresponding internal threads or "female nut" wherein a knob or "winding screw handle" (48) is capable of being rotated to adjust the position of the pulling member in the proximal distal directions (column 3, lines 56-67, column 4, lines 1-4, Fig. 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of the combination of Chin and Young with loosening means, as taught by Goodin et al., to allow the user to control the movement of the pulling member.

16. Regarding claims **14,** Goodin et al. teaches device including a pulling member (36) disposed within a housing (12) wherein a knob or "winding screw handle" (48) is capable of being rotated to adjust the position of the pulling member in the proximal distal directions (column 3, lines 56-67, column 4, lines 1-4, Fig. 2).

17. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chin (US Patent No. 5,391,182) in view of Young (US Patent No. 4,906,231), as applied to claim 4 above, and further in view of Kokernak (US Patent No. 4,583,974).

18. Regarding claim **13**, the combination of Chin and Young discloses a pulling member (20) having a first saw tooth outside surface (22, 23) and a locking member having a second saw tooth (34) (column 2, lines 55-67, Fig. 2, Young). However, the combination of Evans et al. and Young fails to disclose a loosening means including a cover having a third saw tooth on an inside surface of the cover wherein the third saw tooth can be engaged or disengaged with the first saw tooth of the pulling member by opening the cover of the loosening means to adjust the position of the pulling member.

Kokernak teaches a syringe having a threaded shaft (20) of the plunger that is disposed within a housing (15), a loosening means including a latch (26) having threads on its inner circumferential surface that match the threads of the shaft such that when the latch is closed and engaged (Fig. 3) the threaded shaft and plunger can only be moved by rotation of the knob (22) in a screw-type operation and when the shaft is disengaged or pivotally opened the shaft is free to slide axially (column 3, lines 1-15)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a cover to the device of the combination of Chin and Young, as taught by Kokernak, to incrementally control the movement of the pulling member (column 1, lines 65-67).

19. Claims 1, 4, 11, 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. (US Patent No. 5,549,633) in view of Young (US Patent No. 4,906,231).

20. Regarding claim **1**, Evans disclose a loop suture (24) that is threaded through skin around a wide open wound, a tightening member (56) that is capable of gathering both ends of the threaded loop suture to tighten the threaded loop suture and of exerting a pressure of wound tightening force using the loop distal end, a pulling member (54) that is capable of pulling the loop suture through the apparatus (20), and a housing member (28) that houses the pulling member and is capable of making the loop suture tighten by transformation of a pulling force to a wound tightening force when the pulling member pulls the loop suture out of the skin (column 7, lines 22-56, Figs. 4, 7). However, Chin fails to disclose a locking member.

Young teaches a device having a telescoping plunger or "pulling member" (20) within a barrel or "housing" (12) wherein a plunger guide or "locking member" (30) having guide slots (32, 33) and detents (34) that engage the ribs (22) of the pulling member, thus preventing reverse movement of the pulling member (column 2, lines 56-67, Fig. 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of Evans et al. with a locking member, as taught by Young, to prevent reverse movement of a device to ensure safety and control (column 3, lines 1-5, 53-55).

21. Regarding claim **4**, Young discloses a pulling member (20) having a first saw tooth outside surface (22, 23) and a locking member having a second saw tooth (34) on an inside surface of the locking member (30) in reverse form of the first saw tooth on the pulling member to check the movement of the pulling member to prevent slippage in an opposite direction after pulling and engaging the saw teeth of the pulling member and locking member (column 2, lines 55-67, Fig. 2).

22. Regarding claim **11**, Young teaches a loosening means for releasing the over-tightened loop suture by adjusting the position of the pulling member (20) wherein the pulling member can be rotated such that the first saw tooth (23) contact the detents (35) and the foot (27) is removed from engagement under lip (44) such that the pulling member can be pushed toward the distal end of the apparatus (column 3, lines 5-25).

23. Regarding claim **12**, Young teaches device including a pulling member (20), a loosening bolt wherein the locking member (30) includes internal threading and a female nut (44) formed at one end of the housing member (12) (column 3, lines 56-67, column 4, lines 1-4, Fig. 2).

24. Regarding claim **16**, Evans et al. disclose a tightening member that defines an interface between the skin and the apparatus and capable of distributing and buffering even-pressure.

25. Claims 2, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. (US Patent No. 5,549,633) in view of Young (US Patent No. 4,906,231), as applied to claim 1 above, and further in view of Hannam et al. (US Patent No. 5,649,959).

26. Regarding claim **2**, the combination of Evans et al. and Young discloses all of the limitations previously discussed except for an elastic housing member.

Hannam et al. teach a device for sealing a puncture in a vessel having a pulling member (38) telescopically disposed within a housing (32) wherein the housing is formed of flexible or "elastic" material (column 10, lines 1-12).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the housing member of the device of the combination of Evans et al. and Young of an elastic material, as taught by Hannam et al., to enable it to be inserted into awkward locations requiring bending of the housing (column 10, lines 1-12).

27. Regarding claims **5 and 6**, the combination of Evans et al. and Young discloses all of the limitations previously discussed except for strain gauging means.

Hannam et al. teach an elastic member (62) that is connected to a suture (36) (column 14, lines 20-30, Fig. 17).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of the combination of Evans et al. and Young with strain gauging means, as taught by Hannam et al., to retain the suture along the wall of the vessel or wound and to maintain slight pressure thereon (column 14, lines 20-30).

28. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. (US Patent No. 5,549,633) in view of Young (US Patent No. 4,906,231), as applied to claim 1 above, and further in view of Yoon (US Patent No. 5,478,353).

29. Regarding claim **3**, the combination of Evans et al. and Young discloses all of the limitations previously discussed except for a scale marked on the housing or tightening member.

Yoon teaches a method for suturing tissue including a device having pulling member (17) disposed within a housing member (19) wherein the housing member includes a scale (612) to allow the user to control the tension of the suture (column 9, line 18-34).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a scale on the housing member of the device of the combination of Evans et al. and Young, as taught by Yoon, to display and control the amount of tension applied to the wound by the suture (column 9, line 18-34).

30. Claim 7, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. (US Patent No. 5,549,633) in view of Young (US Patent No. 4,906,231), as applied to claim 1 above, and further in view of Kensey (US Patent No. 5,021,059).

31. Regarding claims **7, 9 and 10**, the combination of Evans et al. and Young discloses all of the limitations previously discussed except for a buffering means for buffering the strain force loaded on the loop suture, the buffering means being formed of an elastic member and inserted into a predetermined position of the housing member.

Yoon teaches a method for suturing tissue including a spring (69) that is inserted into a predetermined position of the housing member wherein the spring is located proximal of the pulling member (17)

Kensey et al. teaches a device for sealing punctures in tissue including a pulling member (38) disposed within a housing member (28) wherein a spring (72) is located within the housing (column 8, lines 15-30, Fig. 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the device of the combination of Evans et al. and Young with buffering means, as taught by Kensey, to apply a proximally directed force onto the pulling member to hold the device in a retracted and inoperative position (column 8, lines 15-30).

32. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. (US Patent No. 5,549,633) in view of Young (US Patent No. 4,906,231) and in view of Kensey (US Patent No. 5,021,059), as applied to claim 7 above, and further in view Yoon (US Patent No. 5,478,353).

33. Regarding claim 8, the combination of Evans et al., Young and Kensey discloses all of the limitations previously discussed except for a buffering means formed of an elastic member and inserted into a predetermined position of the pulling member.

Yoon teaches a device having a pulling member formed of a rod (17) inserted within a tubular sleeve (19) and closed with an endcap (65), an elastic member (69) being disposed proximally of the rod, the pulling member being disposed within a housing (21) (Figs. 1, 2) and wherein the elastic member is compressed within the housing between the end cap and the rod (column 6, lines 1-2, Fig. 1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the pulling member of the device of the

combination of Evans et al., Young and Kensey with buffering means, as taught by Yoon, to inhibit unintentional proximal movement and maintain the position of the suture device (column 6, lines 5-9).

34. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. (US Patent No. 5,549,633) in view of Young (US Patent No. 4,906,231), as applied to claims 4 and 11 above, and further in view of Kokernak (US Patent No. 4,583,974).

35. Regarding claim **13**, the combination of Evans et al. and Young discloses a pulling member (20) having a first saw tooth outside surface (22, 23) and a locking member having a second saw tooth (34) (column 2, lines 55-67, Fig. 2, Young). However, the combination of Evans et al. and Young fails to disclose a loosening means including a cover having a third saw tooth on an inside surface of the cover wherein the third saw tooth can be engaged or disengaged with the first saw tooth of the pulling member by opening the cover of the loosening means to adjust the position of the pulling member.

Kokernak teaches a syringe having a threaded shaft (20) of the plunger that is disposed within a housing (15), a loosening means including a latch (26) having threads (49) on its inner circumferential surface that match the threads of the shaft such that when the latch is closed and engaged (Fig. 3) the threaded shaft and plunger can only be moved by rotation of the knob (22) in a screw-type operation and when the shaft is disengaged or pivotally opened the shaft is free to slide axially (column 3, lines 1-15)

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided a cover to the device of the combination of Evans et al. and Young, as taught by Kokernak, to incrementally control the movement of the pulling member (column 1, lines 65-67).

36. Regarding claim **14**, the combination of Evans et al., Young and Kokernak discloses a winding screw (49) for winding the pulling member in order to tighten the loop suture and a winding screw handle (28) for being connected to the winding screw and capable of providing a torque to wind the pulling member (column 3, lines 1-15).

37. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al. (US Patent No. 5,549,633) in view of Young (US Patent No. 4,906,231), as applied to claim 1 above, and further in view of Andreas et al. (US Patent No. 6,355,050).

38. Regarding claim **15**, the combination of Evans et al. and Young discloses all of the limitations previously discussed except for a multiple punctured purse-string type loop suture.

Andreas et al. teach a device for suturing tissue including a purse-string loop suture (246) that is circular suture that is capable of being pulled together to close an opening, the loop suture having multiple anchors (244) or "punctures" to prevent drawing the suture loop completely through the tissue layer (column 19, lines 46-55, Fig. 24).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the loop suture of the device of the

combination of Evans et al. and Young with anchors, as taught by Andreas et al., to close a puncture site or aperture while preventing the drawing of the suture loop completely through the tissue layer (column 19, lines 46-55).

Response to Arguments

39. Applicant's arguments filed 25 November 2009 have been fully considered but they are not persuasive. In response to applicant's argument that Chin is used for suturing two points of facial tissue for deep puncture wounds and that the instant application is for threading a suture through skin around a wide open wound wherein the loop suture penetrates across and tightens the entire wide open wound, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Therefore, the apparatus of Chin is capable of being used to bring together an open skin wound. The Applicant contends that the tightening member of Chin fails to gather both ends of the loop suture at one point. However, Chin discloses the gathering and disposing of both suture ends within the tightening member as seen in Fig. 5E and the suture ends are retracted within the housing with the tightening member as seen in Fig. 5F. The Applicant contends that Chin cannot be regarded as a tightening member since only one end of the central cord (328)/reinversion cord (330) is attached to the membrane (310) which are referenced in Fig. 6, however, the Office Action assigns the claimed features by referring only to Figs.

5 wherein both ends (318) of the suture (316) are disposed within the membrane (310). A new rejection has also been submitted in response to the new claims 15 and 16.

Conclusion

40. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/
3/30/2010
Examiner, Art Unit 3731

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Supervisory Patent Examiner, Art Unit 3731
4/9/10